AmeriWater

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510(K) SUMMARY

June 18, 2013

510(K) Number: K131622

Submitter: AmeriWater

Contact: Brian R. Bowman, Quality & Regulatory Administrator
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Phone: (937)461-8833 Fax: (937)461-1988
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Proprietary Name: AmeriWater MROZ Reverse Osmosis System

SEP 2 0 2013

Common Name: Reverse Osmosis System

Classification Name: Water purification system for hemodialysis

Classification: Class II Medical Device under §876.5665
Panel: Gastroenterology
Product Code: FIP

Predicate Devices: AmeriWater Aseptech Portable RO+ cleared for market under K924695,
AmeriWater MRO systems included in K991519,
AmeriWater MRO Portable RO System cleared for market under K111740

Device Description: The AmeriWater MROZ Reverse Osmosis System is a water treatment system intended for use in hemodialysis applications. The system is designed to remove organic and inorganic substances and contaminants from potable water. The purified (or treated) water will then be used to prepare and dilute dialysate concentrate to form dialysate. The AmeriWater MROZ Reverse Osmosis System is intended to be used in water rooms located in hospitals, clinics, and dialysis centers. There is no direct or indirect contact between the patient and any part of the device nor is the device invasive. Materials that contact the product water include: ABS, Acrylic, Nylon, PVC, Polyester, Polyethylene, Polypropylene, Stainless Steel, Tygon, and Thin Film Composite Membrane (polyimide). The MROZ Reverse Osmosis System purifies water by applying pressure (greater than the osmotic pressure difference) to the feed water to reverse the water flow through a semi-permeable membrane so that the water moves from a more concentrated solution to a less concentrated solution resulting in purified permeate flow. Basically, the feed water is supplied to the membrane where it is split into permeate which has passed through the membrane and the concentrate which passes over the membrane and carries the contaminants to drain. The AmeriWater MROZ Reverse Osmosis System produces water that meets current AAMI and Federal (U.S.) standards for water used in hemodialysis applications.

Indications for Use: The AmeriWater MROZ Reverse Osmosis System is a water treatment device intended for use in hemodialysis applications. It is intended to be used as a component in the AmeriWater Water Purification System (K991519), and is intended to purify potable water for use in making dialysate for hemodialysis and to meet current AAMI and Federal (U.S.) standards. The AmeriWater MROZ is intended for use in water rooms in a hospital, clinic, or dialysis center. The device is intended to be a component in a complete water purification system, and is not a complete water treatment system. It must be preceeded by pre-treatment devices, and may need to be followed by post-treatment devices as well to meet current AAMI and Federal (U.S.) standards. Model MRO3Z is a 3 membrane system designed to supply 6,600 gallons per day (gpd) of product water. Model MRO4Z is a 4 membrane system designed to supply 8,800 gpd of product water. Model MRO5Z is a 5 membrane system designed to supply 11,000 gpd of product water. Model MRO6Z is a 6 membrane systems designed to supply 13,200 gpd of product water. Model MRO7Z is a 7

membrane system designed to supply 15,400 gpd of product water. Model MRO8Z is an 8 membrane system designed to supply 17,600 gpd of product water. Each model is available in a 208V, 230V, or 460V variant and includes a divert- to-drain feature to prevent patient exposure to unsafe product water. Each model includes temperature compensated online monitors that display conductivity and percent rejection. The conductivity monitor activates an audible and visual alarm when the product water conductivity exceeds a preset alarm limit.

Statement of Substantial Equivalence: The AmeriWater MROZ is substantially equivalent to the Aseptech Portable RO+ cleared for market under K924695, the AmeriWater MRO systems included in K991519, and the AmeriWater MRO Portable RO System cleared for market under K111740. The MROZ is the same in design, operation, technology, and intended purpose as the predicate device with the exception that the predicate devices are completely enclosed in a cabinet and a portion of the MROZ is an open frame design. The following table compares and contrasts the predicate devices and the new device. The MROZ is designed to meet the needs of dialysis facilities that require higher product water output than those provided by the predicate devices.

	AmeriWater MROZ	**K991519**	**K924695**	**K111740**
Intended Use	The MROZ is intended for use in hemodialysis applications. It is designed to pre-treat and purify potable water for use in making dialysate for hemodialysis and to meet current AAMI and Federal (U.S.) standards. The MROZ is intended for use in a hospital, clinic, or dialysis center.	The AmeriWater Purification System for Hemodialysis is intended to be used in hemodialysis to remove organic and inorganic substances and microbial contaminants from water. Purified (or treated) water will then be used to prepare and dilute dialysate concentrate to form dialysate and/or rinse dialyzers for multiple use.	The Aseptech Portable RO+ is a standalone water treatment system for use in hemodialysis applications. It is designed to pre-treat and purify potable water for use in making dialysate for hemodialysis. The Aseptech Protable RO+ is intended to be used in hospitals, clinics, home care, and dialysis centers.	The AmeriWater MRO Portable Reverse Osmosis Systems are water treatment systems intended for use in hemodialysis applications. They are designed to pre-treat and purify potable water for use in making dialysate for hemodialysis and to meet current AAMI and Federal (U.S.) standards. The MROS model is intended for use in a hospital, clinic, dialysis center, or for home care for single patient use. The AmeriWater Portable MRO1 model is for treatment of up to two patients in a hospital, clinic, or dialysis centers.
Technology	Reverse Osmosis	Reverse Osmosis	Reverse Osmosis	Reverse Osmosis
Enclosure	Open frame with partial cabinet, stationary (no casters)	Cabinet with casters	Cabinet with casters	Cabinet with casters
Water Contacting Materials	ABS, Acrylic, Nylon, PVC, Polyester, Polyethylene, Polypropylene, Stainless Steel, Tygon, and Thin Film Composite Membrane (polyimide)	ABS, Acrylic, Nylon, PVC, Polyester, Polyethylene, Polypropylene, Stainless Steel, Tygon, and Thin Film Composite Membrane (polyimide), Carbon	ABS, Acrylic, Nylon, PVC, Polyester, Polypropylene, Stainless Steel, Tygon, and Thin Film Composite Membrane (polyimide), Carbon, Resin - petreated	ABS, Acrylic, Nylon, PVC, Polyester, Polyethylene, Polypropylene, Stainless Steel, Tygon, and Thin Film Composite Membrane (polyimide), Carbon
Power Requirements	208V/230V/460V, 60Hz, 20A	115V/ 208V/230V/460V, 60Hz, 20A	115V, 60Hz, 20A	115V, 60Hz, 20A
Minimum Feed Pressure	20 psi	20 psi	20 psi	20 psi
Maximum Feed Pressure	50 psi	90 psi	90 psi	50 psi
Maximum Output Product Water	17,600 gpd	6,000 gpd	2,400 gpd	1,296 gpd

Summary of Performance Testing: Non-clinical testing was conducted to verify and validate the performance of the reverse osmosis function. Results of performance testing indicate that the device produces water that meets current AAMI and Federal (U.S.) standards. Test results from biocompatibility testing, performance testing, and electrical safety testing indicate that the device is safe and effective for its intended purpose.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 20, 2013

AmeriWater, Inc.
% Brian R. Bowman
Quality and Regulatory Administrator
1303 Stanley Avenue
Dayton, OH 45404

Re: K131622
Trade/Device Name: AmeriWater MROZ Reverse Osmosis System
Regulation Number: 21 CFR§ 876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: FIP
Dated: August 19, 2013
Received: August 22, 2013

Dear Brian R. Bowman,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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INDICATIONS FOR USE

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Prescription Use__X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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